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January 12, 2007

David Saliwanchik

David R. Saliwanchik, Patent Attorney

INFORMATION DISCLOSURE
STATEMENT
Patent Application
Docket No. GJE-7462CXC1
Serial No. 10/578,692

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : *Not yet assigned*

Applicant(s) : Rajiv Nayar, Mark Manning, Philip J. Barr, Philip A. Pemberton, Ian C. Bathurst,
Helen Gibson

Serial No. : 10/578,692

Filed : May 10, 2006

For : Dry Recombinant Human Alpha 1-Antitrypsin Formulation

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§1.97 AND 1.98

Sir:

The above-identified patent application was filed in the U.S. Patent Office as a national application under 35 USC §371. A copy of the International Search Report and copies of the references cited therein have been made available in the national stage file.

However, for the examiner's convenience, the applicants are attaching a copy of the International Search Report as well as copies of the documents cited in the International Search Report. Also attached is Form PTO/SB/08 listing the references.

In accordance with 37 CFR §1.56, the applicants hereby request that the references cited in the International Search Report and listed on the attached form PTO/SB/08 be made of record and considered in the examination of the subject application. If any additional fee is required, or to credit any overpayment, please use Deposit Account No. 19-0065.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

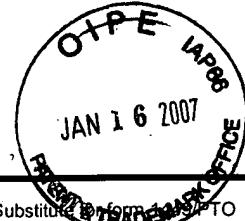
Respectfully submitted,



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DRS/wrc

Attachments: Form PTO/SB/08 (2 pages)
International Search Report
Copies of references cited (5)



Substitute for TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

1

of

2

Complete if Known

| | |
|------------------------|------------------|
| Application Number | 10/578,692 |
| Filing Date | May 10, 2006 |
| First Named Inventor | Rajiv Nayar |
| Art Unit | Not yet assigned |
| Examiner Name | Not yet assigned |
| Attorney Docket Number | GJE-7462CXC1 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|--|--------------------------------|--|---|
| | | Number - Kind Code ² (if known) | | | |
| U1 | US- | | | | |
| U2 | US- | | | | |
| U3 | US- | | | | |
| U4 | US- | | | | |
| U5 | US- | | | | |
| U6 | US- | | | | |
| U7 | US- | | | | |
| U8 | US- | | | | |
| U9 | US- | | | | |
| U10 | US- | | | | |
| U11 | US- | | | | |
| U12 | US- | | | | |
| U13 | US- | | | | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|---------------------------|---|--|---|----------------|
| | | Country Code ³ | - Number ⁴ - Kind Code ⁵ (if known) | | | |
| F1 | WO | 96/32152 | 10-17-1996 | Inhale Therapeutic Systems | All | |
| F2 | WO | 98/16205 | 04-23-1998 | Inhale Therapeutic Systems | All | |
| F3 | WO | 00/54797 | 09-21-2000 | Novartis AG | All | |
| F4 | WO | 2004/060528 | 07-22-2004 | Aventis Behring, L.L.C. | All | |
| F5 | | | | | | |
| F6 | | | | | | |
| F7 | | | | | | |
| F8 | | | | | | |
| F9 | | | | | | |

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|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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|--|---|----|---|--------------------------|------------------|
| <p>Substitute for form 1449/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p> | | | | Complete if Known | |
| Sheet | 2 | of | 2 | Application Number | 10/578,692 |
| | | | | Filing Date | May 10, 2006 |
| | | | | First Named Inventor | Rajiv Nayar |
| | | | | Art Unit | Not yet assigned |
| | | | | Examiner Name | Not yet assigned |
| | | | | Attorney Docket Number | GJE-7462CXC1 |

| NON PATENT LITERATURE DOCUMENTS | | | | |
|--|-----------------------|---|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | | T ² |
| | R1 | VEMURI, S. et al., "Effect of Cryoprotectants on Freezing, Lyophilization, and Storage of Lyophilized Recombinant Alpha ₁ -antitrypsin Formulations," <i>PDA Journal of Pharmaceutical Science and Technology</i> , 1994, pages 241-246, Vol. 48, No. 5. | | |
| | R2 | | | |
| | R3 | | | |
| | R4 | | | |
| | R5 | | | |
| | R6 | | | |
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|--------------------|--|-----------------|
| Examiner Signature | | Date Considered |
|--------------------|--|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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